Remarks

In the interest of clarity, the paragraph numbers hereafter match the paragraph numbers in the Office Action.

As an initial matter, Applicant thanks the Examiner and the Examiner's supervisor for the interview that was conducted on August 3, 2010 in which we discussed changes to the claims that may better distinguish the claims of this application over the cited references. Applicant still believes that the previously presented claims are patentable over the cited references and therefore includes the previous set of claims above and related reasoning for patentability below.

In addition, Applicant has added new claims 239 through 241. Claim 241 includes the limitations that we discussed during an interview in late September. In the event that at least a subset of the new claims are allowable, Applicant may opt to change dependencies of the previously presented dependent claims so that those claims depend from the new independent claim or to amend the previous independent claims to include at least a subset of the new limitations in all of the claims.

4. Applicant thanks the Examiner for indicating that claims 194-200 and 221-230 are allowed.

5-7. Applicant has not placed claims 234-237 in independent form at this time as the rejections of the base claims (e.g., claim 1) have been refuted below.

8-9. The Office Action rejected each of claims 1, 21, 22, 23, 24, 201, 206, 207, 212, 213, 214, 215, 216, 217, 219, 220, 231, 232, 233 and 238 as obvious over Gombrich in view of Kerns. Applicant strongly traverses this rejection.

Claim 1 requires, among other things, (1) providing a device identifier that includes information identifying a medical device within a communication network; (2)

using a portable data collector to obtain the device identifier information from the device identifier when the data collector is spatially proximate the device identifier; (3) transferring the device identifier information to a controller; (4) using the device identifier information to associate the controller with the medical device so that the controller can communicate with the medical device; and (5) causing the controller to send a communication to the medical device and receiving the communication at the medical device.

The Examiner has indicated that Gombrich fails to teach or suggest requirement (5). The Office Action indicates Gombrich teaches all of requirements (1) through (4). Nevertheless, Applicant is absolutely clear that Gombrich fails to teach any of requirements (1) through (4).

Regarding the requirement of (1) providing a device identifier that includes information identifying a medical device within a communication network, the device identifier information must be usable to identify a specific device within a communication network as opposed to an item that may be administered to (e.g., a medication) or performed (e.g., a test) on a patient. For instance, a medical device may be an IV pump or the like. A medication to be administered to a patient is not a medical device that can be identified within a communication network. Similarly, a test or procedure is not a medical device that can be identified within a communication network.

Gombrich teaches a system for verifying that specific items that are to be administered to or performed on a patient are associated with the patient prior to administration. For example, where a test is to be performed on a patient, a nurse may use a reading device to read a patient ID from a wristband and information on a label placed on a patient's chart that specifies the test to be performed and the patient for whom the test was prescribed. Gombrich teaches that the information is presented to a controller which compares the patient information from the wrist band to the information from the test label and when the information corresponds, a green light is illuminated to indicate that the test should be performed. In this example, the test and patient

information from the test label is not usable to identify a medical device within a communication network.

As another example, where medication is to be administered to a patient, a system user may use a reading device to read a patient ID from a wristband and information from a label on a vial that specifies a medication located in the vial as well as a patient for whom the medication was dispensed. Gombrich teaches that the information is presented to a controller which compares the patient information from the wrist band to the information from the vial and when the information corresponds, a green light is illuminated to indicate that the test should be performed. In this example, the medication and patient information from the vial only specify a medication and patient and is not usable to identify a medical device within a communication network.

Thus, Gombrich only teaches labels that specify administrable medications or tests as opposed to labels (i.e., device identifiers) that can be used to identify a medical device within a communication network. Consistent with this understanding of Gombrich, Applicant has scoured Gombrich (for yet a third time in response to multiple Office Actions) and is clear that Gombrich never once contemplates a device identifier on any type of device that can be used to identify the device within a communication network.

Highlighting the distinction between a medical device of claim 1 and Gombrich's vial (i.e., a medication delivery container) that specifies a patient for whom a medication has been dispensed, currently pending claim 12 further limits claim 1 by requiring that patient information be stored on an information device where the information device may be a medication delivery container (e.g., a vial), establishing a link between the information device and the medical device and transferring the patient information from the information device (e.g., the vial) to the medical device. Thus, in claim 12, clearly a medical device and an information device (i.e., a vial) are completely separate components within the claimed system. In addition, referring to Kerns (i.e., the second reference cited as obviating claim 1 along with Gombrich), Kerns itself teaches that a

medication delivery container (e.g., an IV bag) 28, 30) is different than a medical device such as an IV pump 16, 22.

Thus, while Gombrich teaches obtaining information from a test label or a vial, the obtained information does not identify a medical device within a communication network and instead identifies an administrable medication or test/procedure.

With respect to the sections of Gombrich cited I the Office Action as teaching requirement (1), col. 2, lines 38-47 lists types of items that may be associated with a patient and the list includes drugs, blood test samples, IV's, surgical procedures, etc., none of which is a medical device that can be identified within a communication network. Cited col. 3, lines 21-30 simply teach that a reader can obtain item identifying information generally and does not teach or suggest an identifier that includes identifying information for identifying a medical device on a communication network. Cited col. 9, lines 49 through 65 simply describe different aspects of a reader device and teach nothing additional about identifying information or identification of a medical device on a network.

In the event that the Examiner maintains the current rejection, Applicant requests that the Examiner clearly point out where Gombrich even remotely suggests providing a device identifier that includes device identifying information identifying a medical device within a communication network.

Regarding the requirement of (2) using a portable data collector to obtain the device identifier information from the device identifier when the data collector is spatially proximate the device identifier, while Gombrich does teach obtaining information from a vial (e.g., a medical device), the information obtained in claim 1 has to include information identifying a medical device within a communication network. Again, none of Gombrich's medication or test labels includes information identifying a medical device on a communication network.

Regarding the requirement of (3) transferring the device identifier information to a controller, again, because Gombrich fails to teach or suggest obtaining "medical device"

identifier information, Gombrich cannot teach or suggest transferring such information to a controller.

Regarding the requirement of (4) using the device identifier information to associate the controller with the medical device so that the controller can communicate with the medical device, Gombrich teaches nothing about associating a controller with a medical device in any way, much less using device identifier information obtained from a medical device to associate a controller with a medical device. With respect to the sections of Gombrich cited as teaching requirement (4), col. 2, lines 35-47 teach that one object of Gombrich is to provide a cross check to ensure that an identified item properly corresponds to an identified patient. Correspondence between a patient and an item has absolutely nothing to do with associating a controller with a medical device.

Thus, Gombrich fails to teach any of claim 1 requirements (1) through (5) as indicated above.

Turning to Kerns, Applicant agrees that Kerns teaches a controller that sends a communication to a medical device and that the device receives the communication. However, the Office Action relies on Gombrich as teaching claim 1 requirements (1) through (4) which Gombrich fails to teach as indicated above. Kerns also fails to teach requirements (1) through (4). Because both Gombrich and Kerns fail to teach or suggest requirements (1) through (4) as indicated above, the combination of Gombrich and Kerns cannot possibly teach the limitations (1) through (4).

In addition, the claim 1 preamble requires a controller that is remote from a medical device. Kerns specifically requires a controller and medical devices that are physically and electrically connected within a single rack system (see Kerns' claim 1 that requires a management unit (e.g., controller) and modules (e.g., medical devices) top be structurally and electrically connected as well as Kern's Figs. 1 and 4a through 4e and Kerns' specification generally that teach electrical and physical connection of a

controller and devices). Clearly controller 14 in Fig. 1 is not remote from the medical devices 16-22 it is associated with.

The MPEP indicates that if a proposed modification would render a prior art invention unsatisfactory for its intended purpose, then there would be no suggestion or motivation to make the proposed modification (see MPEP 2143.01(V)).

The whole idea behind Kerns' invention is that a controller is directly linked to medical devices that are to be controlled thereby so that there is no confusion regarding which devices are controlled/controllable by which controller in emergency or other types of complex medical settings (see Kerns' Abstract, col. 7, lines 38-45 and Kerns' claim 1 that requires structural and electrical connection between a management unit (e.g., a controller) and modules (e.g., medical devices)). It is unclear how a portable data collector as in Gombrich could be combined with Kerns' system to yield the claim 1 invention without rendering Kerns' invention inoperable for its intended purpose. In this regard, if a portable device were to be used to obtain information from a medical device and to provide that information to Kern's controller 14, there would be no need for Kern's direct linkage of medical devices to the controller 14 and the physical link which is central to Kerns' invention would not serve its intended purpose.

Moreover, even if Kerns and Gombrich were to be combined, the combination would not yield the claim 1 invention. To this end, as described above, Gombrich teaches medical vials or other medication deliver containers such as IV bags that include medication specifying labels or tags that can be read to confirm that medications in the containers are to be delivered to a specific patient. Kerns teaches a system for associating medical devices such as IV pumps 16, 22 with a controller 14 via a physical linkage where prescription information is entered manually by a system user (see Kerns' col. 6, lines 21-35) where the system includes both medical devices 16-22 and medication delivery containers 28, 30. Thus, Gombrich's medical delivery containers are akin to Kerns' medical delivery containers 28, 30 and combining the two references, at best, would result in a system where Gombrich's medical delivery containers are

swapped in for Kerns' containers 28 and 30. In this case, Kerns' system would operate essentially as described in the Kerns' specification and Gombrich's system would operate in parallel there with. Thus, Kern's system would operate to associate medical devices 16-22 with controller 14 via the physical linkage and Gombrich's label reading device would be used in parallel to obtain information from IV bags 28 and 30 and a patient wrist band to be provided to controller 14 for comparison and indication when medication in a bag is to be administered to a specific patient. In short, a Kerns/Gombrich combination would result in parallel processes for (1) medication verification and (2) medical device/controller association as opposed to one synergistic process as required by claim 1.

Thus, because the combination of Kerns and Gombrich as suggested by the Examiner would render Kerns' invention unsuitable for its intended purpose, the two references should not be combined. In addition, because neither of Kerns nor Gombrich teach or suggest all of the claim 1 limitations, even if the references are combined, the resulting system cannot obviate claim 1. Moreover, even if Kerns and Gombrich are combined, the combination would result in parallel processes as opposed to a single synergistic process for associating medical devices with a controller. For all of these reasons the combination of Kerns and Gombrich does not obviate claim 1 and Applicant requests that the current rejection of claim 1 be withdrawn.

Regarding claim 21, claim 21 requires that the medical device be an infusion pump. While Kerns teaches infusion pumps, again, Kerns also teaches IV bags to be used with the infusion pumps. As recognized by the Examiner, Gombrich fails to teach infusion pumps and instead teaches special medications, IVs, etc., that are dispensed in containers where the IV bags are to be used with IV pumps/medical devices as in Kerns. Combining Gombrich and Kerns, Gombrich's medication containers would be swapped for Kerns' medication containers as opposed to for Kerns' medication devices and two separate procedures as specified in Gombrich and Kerns would result as

opposed to a single procedure. Similar reasoning is applicable to claims 206 and 214 that requires an infusion pump medical device.

In addition, claim 206 requires transmission of a signal from an infusion pump to the controller indicating that the infusion pump is no longer operative and disassociating the controller from the pump upon receiving the signal. The Office Action cites Gombrich as teaching this limitation even though the vial and test labels (i.e., the components in Gombrich that the Examiner appears to read on the medical devices) are "dumb" in the sense that they simply yield stored information and cannot perform any processing such as identifying when a pump is no linger operative. For this additional reason claim 206 is patentable over the cited references and Applicant requests that the current rejection be withdrawn.

Claim 209 further limits claim 1 by requiring use of the portable data collector to obtain information from each of a medical device and a medication container, among other thing. Gombrich fails to teach or suggest obtaining information from each of a medical device (e.g., an IV pump) and a medication container (e.g., an IV bag). Again, all Gombrich teaches is obtaining information form a container label. Similar reasoning is applicable to claim 212 which requires using a collector to obtain information from a medication container. For at least this additional reason claims 209 and 212 are each patentable over the cited references and Applicant requests that the current rejections be withdrawn. In the event that this rejection is maintained Applicant requests that the Examiner indicate where Gombrich or any other cited reference teaches or suggests obtaining information from each of a medical device and a separate medication container (currently the Examiner appears to be double counting the vial label as both a device and a container).

Claim 232 includes limitations that are similar to the limitations of claim 1 and therefore should be patentable over the cited references for the reasons discussed above with respect to claim 1.

Claim 238 includes limitations that are similar to the limitations of claim 1 and therefore should be patentable over the cited references for the reasons discussed above with respect to claim 1.

10. The Office Action rejected each of claims 2-20, 193, 202, 203 and 208-211 as obvious over Gombrich in view of Kern and further in view of Examiner's official notice. Regarding claims 3, 4, 7, 10, 12, 16, 202 and 203 , Applicant strongly traverses this rejection for additional reasons.

Claim 3 requires that the first communication be wireless. The Office Action indicates that it would be obvious to modify Gombrich so that the first communication from a controller to a medical device would be wireless. The October 29, 2008 Office Action and subsequent Office Actions have admitted that Gombrich does not teach or suggest that a controller transmit a first communication to a medical device. Thus, even if Gombrich to be modified, it is unclear how making Gombrich's communications wireless could result in a controller to medical device wireless communication when Gombrich fails to contemplate the underlying first communication itself. Kerns' communications are all via a physical and electrical link which is required to achieve Kerns' primary purpose and therefore it would make no sense to use wireless controller-to-medical device communications in that reference. For at least this additional reason claim 3 and claims that depend there from are patentable over the cited references and Applicant requests that the current rejections be withdrawn.

Claim 4 further limits claim 1 and requires that the step of the controller sending a communication to a medical device includes transmitting a controller address to a medical device. The Office Action cites Gombrich col. 15, lines 9-48 as teaching this requirement. Applicant has examined the cited section of Gombrich and that section teaches nothing about transmitting any information from a controller to a medical device, much less a controller address. Instead, the cited section teaches that a portable data collector can transmit information to a controller. Transmission from a

collection device to a controller is completely different than transmission from a controller to a medical device.

In addition, the rejection of claim 4 is laid out in the October 29, 2008 Office Action. In that Action and subsequent Actions, the Examiner has admitted that Gombrich fails to teach or suggest causing a controller to send a communication to a medical device and yet the Examiner cites Gombrich as teaching the claim 4 controller-to-medical device controller address transmission limitation. If Gombrich fails to teach the first communication in claim 1 how could Gombrich teach the first communication in claim 4? For at least this additional reason claim 4 is patentable over the cited references and Applicant requests that the current rejection be withdrawn.

Claim 7 requires a second wireless communication from the medical device in response to first wireless communication received form the controller. The Office Action indicates that it would be obvious to modify Gombrich in this fashion. The October 29, 2008 Office Action and subsequent Office Actions have admitted that Gombrich does not teach or suggest that a controller transmit a first communication to a medical device and therefore it is unclear how it would be obvious in Gombrich to have a medical device transmit a second wireless communication in response to an absent first communication. For at least this additional reason claim 7 and claims that depend there from are patentable over the cited references and Applicant requests that the current rejections be withdrawn.

Claim 10 requires that a medical device from which device identifier information is received compares first and second patient information sets. The Office Action cites Gombrich as teaching this limitation. Gombrich teaches that a remote controller, not a medical device, perform a comparison. For Gombrich to teach that a device from which identifying information is obtained performs a comparison, Gombrich would have to teach that a device/bar code that indicates a medication on a vial or that specifies a test performs the comparison and that data is transmitted to the device by the controller to perform the comparison. As discussed above, Gombrich fails to teach or suggest

transmitting information to a vial or test specifying device and vial and test specifying devices do not perform any type of comparison in Gombrich. For at least these additional reasons claim 10 and claims that depend there from are patentable over the cited references.

Claim 12 further limits claim 1 by requiring that a first patient information set be stored on an information device that may be a medication delivery container (e.g., an IV bag, a vial, etc.), establishing a link between the information device and the medical device and transferring the first patient information set to the medical device. The Office Action cites Gombrich as teaching this limitation at col. 2, lines 5-47. Applicant has examined the cited section of Gombrich which only teaches a portable device for obtaining information from labels on vials or the like where the obtained information is then provided to a controller for comparison to other data. In the Action the Examiner has already interpreted Gombrich's medication vials to be medical devices and therefore those same vials cannot also read on the medication delivery containers of claim 12 from which patient information is transmitted to the medical device. In short, claim 12 requires two devices (i.e., a medical device and a separate information device) where Gombrich only teaches a single device. Similar reasoning is applicable to claim 13 where the information device is an IV bag. For at least this additional reason claims 12 and 13 are patentable over the cited references and Applicant requests that the current rejection be withdrawn.

Claim 16 requires that a second patient information set be obtained from a patient mounted device and be provided to a medical device where the medical device performs a comparison of the second patient information set to a first patient information set. Again, Gombrich teaches a system where a central controller, not a medical device, performs a comparison of first and second patient information sets which is complete different than claim 16. For at least this additional reason claim 16 and claims that depend there from are patentable over the cited references.

Claim 202 requires that the device identifier information include a medical device address. The Office Action cites Gombrich as teaching that a device identifier includes a medical device address. The sections of Gombrich cited as teaching this limitation do not do so. Again, each of Gombrich's labels specifies either a medication or a test procedure that has been prescribed for a patient. A medication or procedure would not have a device address associated with it. For at least this additional reason claim 202 and claims that depend there from are patentable over the cited references.

Claim 203 requires that after a controller and medical device are associated, the medical device transmitting information to the controller. The Office Action cites col. 15, lines 9-48 as teaching this limitation. The cited sections of Gombrich only teach that a portable device can be used to obtain information from a vial or test label which is then transmitted by the portable device to a controller. Thus, in Gombrich, the vial or test label (i.e., the component that the Examiner appears to be reading as a "medical device") does not transmit anything to a controller and instead, the portable device obtains label information which is transmitted to a controller. In addition, the portable device reading and transmission in Gombrich is before there would be any association of a medical device and a controller as opposed to after as required by claim 203. For these additional reasons claim 203 is patentable over the cited references and Applicant

12. With respect to the Examiner's arguments that Gombrich teaches a controller that communicates with medical devices, Applicant strongly traverses. Assuming that Gombrich's base station can be considered a controller as suggested by the Examiner, Gombrich only teaches that the base station/controller communicates with the portable hand held terminal (see Gombrich quite in the Office Action – col. 4, lines 56-64). The portable hand held terminal in Gombrich is not a medical device and Gombrich fails to teach or even remotely suggest that the base station/controller communicates in any fashion with a medical device or, for that matter, a vial or test label, which appear to be the components that the Examiner is citing in Gombrich as

medical devices. While using a controller to communicate with a medical device is taught in Kerns, again, if Gombrich and Kerns were to be combined, the resulting system would include parallel processes wherein (1) Gombrich's process would be performed to confirm medications are to be administered to a specific patient and (2) Kerns' system/process would be used to physically associate pumps with a controller and the single synergistic system envisioned by the Examiner clearly would not be contemplated.

Applicant has introduced no new matter in making the above remarks and amendments. In view of the above remarks and amendments, Applicant believes claims 1-24, 193-217 and 219-239 of the present application recite patentable subject matter and allowance of the same is requested. No fee in addition to the fees already authorized in this and accompanying documentation is believed to be required to enter this amendment, however, if an additional fee is required, please charge Deposit Account No. 17-0055 in the amount of the fee.

Respectfully submitted,

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